

REMARKS

The Examiner objected to the application's drawings, citing deficiencies in the drawings. Applicant thanks the Examiner for her attention to detail, and has amended the drawings to provide a lead line to element 106 in Fig. 1 to fully respond to each objection.

The Examiner has rejected Claims 3, 4 and 5 based on 35 U.S.C. 112 as being indefinite. Corrections are made herein by cancelling the double inclusion of the face mask.

The Examiner has rejected Claims 2, 3 and 5 based on 35 U.S.C. 103(1) as being unpatentable over Hickle et al. (US 5,676,133) in view of Wright (US 2,222,971). Applicant traverses such rejection and responds to the rejection.

The device described by the patent issued to Hickle, et al, is a mask that is adherent, or in the least, tightly sealed with the patient's skin surface. "The external side of the film 30 has an annular area 32 which carries an adhesive 34 for bonding to the peripheral edge 20 of the mask base 18 to join the two together. To then seal the mask to the patient's face, an internal annular area 36 carries an adhesive 34 that, until use, is covered by backing 38. To apply the mask to the patient, the backing 389 is stripped away from the film 30 and the mask 16 is generally centered upon the patient's face. Light pressure is then applied to section 36 of the film 30 to obtain a sealing engagement between the patient's face and the mask 16 so as to

preclude the escape of patient exhalations from between the face and the film 30." (column 8, lines 43 - 54)

Hickle, as well as Wright, teaches a device that is held tightly to the surface of the face, whereas the present invention teaches a device, that is held to the face without a seal, and, by nature of having a one way valve, allows the inflow of ambient air. Such a function is the opposite of Hickle's and Wright's tightly fitting devices. The present invention may have a partial sealing portion but is not completely sealed to the user's face, as opposed to the Hickle and Wright devices that are completely sealed to the user's face.

The seal to the patient's face is so important to the Hickle device that there is provided a cross sectional increased thickness for purposes of providing rigidity against collapse upon a patient's inhalation and of providing rigidity to facilitate a sealed interlock or coupling of the opening 25 to an associated cover adapter 50 (See generally, column 9, lines 12 - 19).

One could not combine an inflow, one-way flapper valve with the Hickle device and accomplish that which is taught by Hickle, in that the presence of a flapper valve would allow the free inflow of air into the Hickle device, which is contrary to the taught method of having an adherent seal with the patient's skin at the point of contact with the mask.

Hickle teaches a gas evacuation system that is coupled to the mask with a standard gas circuit and functions in conjunction

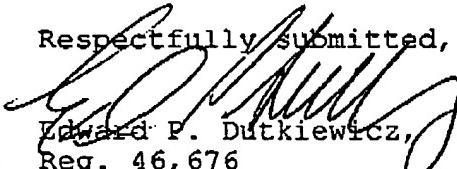
with a pressurized gas source. Hickle teaches a device that has a plurality of valves. See elements 242, 244, and 246 of Figure 18. The valves are on the inspiratory side and the expiratory side of the circuit that is connected there to. While Hickle uses many valves, all of their functions is performed by one valve of the current invention, which, unlike Hickle, is part of the mask. The present invention teaches a single one way valve that allows a person to breath at a rate of gas flow greater than that provided by the system.

In the present invention, any negative pressure induced in the mask is immediately responded to by the opening of the one-way flapper valve. In the Hickle device, negative pressure must be transmitted out of the mask and through the length of the breathing circuit before a valve can open. Such a device is far less efficient than the present invention. Functionally, the proximity of the valve on the mask surface allows a more rapid response to negative pressure.

In addition, the loose fit of the present invention, evidenced by the partial seal, also removes the safety requirement that a valve be provided to prevent over pressurization of the mask. The loose fit, as well as the large bore exhaust conduit prevent any over-pressurization from occurring. The teaching of a partial seal on the face recipient area is contrary to the teachings of Wright, which teaches a tightly sealed mask that does not allow any passive mixture of ambient air into the user's air intake space.

Examiner rejects Claims 2 and 4 under 35 U.S.C. 103(a) as being unpatentable over Hickle et al, in view of Macris et al. (U.S. 5,989596). Like the Hickle and Wright inventions, the Macris invention is founded on the principle of maintaining a continuous positive airway pressure, also known as CPAP. Such a principle requires a tightly fitting mask, which is contrary to the present invention. Neither Hickle, Wright, nor Macris describe an embodiment of their invention that may have a partial cuff, or partial seal. See Figs 4, 5, and 6, and element 27 of the present application. The reasonable implication of a partial cuff is a partial seal. None of the cited prior art teaches such a configuration.

Claim 2, and therefore dependent Claims 3, 4, and 5 has been amended to include the limitation of the partial seal, which is not found in the cited prior art. Applicant therefore submits that the amendments fully respond to, and overcome, the Examiner's objections and rejections. The Applicant respectfully requests that the Examiner withdraw her rejections and pass this application forward to issue.

Respectfully submitted,

Edward P. Dutkiewicz,
Reg. 46,676
640 Douglas Avenue
Dunedin, FL 34698
(727) 734-2855